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Xin Qi

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04/15/2009

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EXAMINER

HOLLOMAN, NANNETTE

ART UNIT

PAPER NUMBER

1612

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|--------------------------------------|----------------------------------|--|
| Office Action Summary | Application No. 10/578,551 | Applicant(s) QI ET AL. | |
| | Examiner NANNETTE HOLLOMAN | Art Unit 1612 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-4, 10-17, 31 and 33-35 is/are pending in the application.
- 4a) Of the above claim(s) 34 and 35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-4, 10-17, 31 and 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' arguments, filed January 26, 2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Election/Restrictions

Newly submitted claim 34 and 35 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Group I, claim(s) 2-4, 10-17, 31 and 33, drawn to a method of treating hypoglycaemia in an individual.

Group II, claim(s) 34, drawn to a method of treating glycogen storage disease in an individual.

Group III, claim(s) 35, drawn to a method of treating liver disease in an individual.

The technical feature linking the claims is administering a food composition. Prior art exists which causes the method in the current application to lack a special

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technical feature. Bohrmann et al. (USP 4,418,090) disclose a food product, which meets the limitation of administration (Abstract).

As a result, no special technical feature exists among the different groups because the inventions in Groups I-III fail to make a contribution over the prior art and are therefore not "special."

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 34 and 35 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 102 (Previous Rejection)

Claims 1-3, 5, 17 and 33 were rejected under 35 U.S.C. 102(b) as being anticipated by Bohrmann et al. (US Patent No. 4,418,090). This rejection is maintained.

Applicant's Argument

Applicant argues Bohrmann provides no teaching of using the food product to treat any disease. Applicant's arguments have been fully considered but they are not persuasive.

Examiner's Response

While Bohrmann et al. do not mention the claimed uses; following the teaching of Bohrmann et al. one would ingest the food product which contains heat- moisture treated starches and thus inherently perform the same function as claimed herein to

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treat hypoglycaemia. It is known that the consumption of starch by a human increases glucose levels¹, which would in fact treat hypoglycaemia.

Claim Rejections - 35 USC § 103 (New Rejection)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

¹ Metabolic Energy (Stryer, Biochemistry, Metabolic Energy, Third Edition, p. 342, 1988, previously disclosed). This reference is used to disclosed that starch is hydrolyzed into glucose when ingested by humans and is not relied upon for the basis of the rejection.

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1) Claims 4, 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bohrmann et al. (US Patent No. 4,418,090) in view of Schmedel et al. (US Patent Publication No. 2003/0054501).

Bohrmann et al. which is directed to a food product, discloses the use of heat moisture treated starches (claim 5) (Abstract and column 6, lines 32-35). Bohrmann et al. discloses a food composition that contains greater than 50 g of starch (claim 17) (column 8, line 21). The food product is being understood to meet the limitation of “kit” in instant claim 31. It is known that the consumption of starch by a human increases glucose levels², which would in fact treat hypoglycaemia.

Bohrmann et al. differs from the instant claims insofar as it does not disclose a waxy starch.

Schmedel et al. disclose a food composition with waxy maize (corn) starches (claim 14 and 33) (paragraphs [0018]-[0019]). Schmedel et al. further discloses a hydrothermally treated starch (claim 4) (paragraph [0028]). Schmedel discloses the waxy starch has amylase content of <10% (claim 13) (paragraph [0033]). The instant specification defines a “waxy” starch as containing <20% amylase (80% amylopectin) (Specification, p. 19, lines 17-18). Schmedel et al. disclose the process of using hydrothermally treated waxy starches improves the quality and quantity of products made (paragraph [0017]).

Schmiedel et al. differs from the instant claims insofar as it does not disclose heat moisture treated or annealing treated starches.

It would have been obvious to have used waxy starch in the food product of Bohrmann et al. motivated by the desire to produce a product of improved quality at a larger quantity as disclosed by Schmiedel et al.

The instructions of instant claim 31 are non-functional descriptive material. Patentable weight need not be given to printed matter absent a new and unobvious functional relationship between the printed matter and the substrate. See MPEP § 2106.01.

2) Claims 10-11 and 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bohrmann et al. (US Patent No. 4,418,090) in view of Kaufman (US Patent Publication No. 2003/0054501 A1, previously disclosed).

Bohrmann et al. is discussed above and differs from the instant claims insofar as it does not disclose individuals with glycogen storage disease or diabetes (Type I or II).

Kaufman discloses a therapeutic food composition containing starch for treatment of diabetic patients to prevent hypoglycemic episodes and diminish fluctuations in blood sugar levels (claims 1-3 and 33) (Abstract). Kaufman further discloses treating patients having glycogen storage disease and Type I or II diabetes (claims 10-11) (column 1, lines 64-65 and column 2, lines 46). Kaufman discloses maintaining blood sugar levels above 60 mg/dl (converted to 3.33mmol/l) for as long as

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8-9 hours, which meets the limitation of instant claims 15 and 16 (column 4, lines 28-30).

Kaufman differs from the instant claims insofar as it does not disclose a therapeutic food composition containing heat moisture treated or annealing treated starch.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the heat moisture-treated starch of Bohrmann et al. as the food product of Kaufman motivated by the desire to diminish fluctuations in blood sugar levels and treat glycogen storage disease and diabetes (Types I and II) as disclosed by Kaufman.

3) Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bohrmann et al. (US Patent No. 4,418,090) in view of Hansson et al. (WO 02/34271 A1, previously disclosed).

Bohrmann et al. is discussed above and differs from the instant claims insofar as it does not disclose individuals with liver disease.

Hansson et al., which is directed to a composition of heat treated starch for the prevention of hypoglycaemia in patients with diabetes or liver disease (instant claim 1-3, 11-12 and 33) (Abstract and p. 8, lines 9-11, claim 6), discloses a method for stabilizing the blood sugar levels and avoiding the oscillation between unhealthy high and low blood sugar levels (p. 8, lines 27-28).

Hansson et al. differ from the instant claims insofar as it does not disclose a heat moisture-treated starch or annealing-treated starch.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the heat moisture-treated starch of Bohrmann et al. as the food product of Hansson et al. motivated by the desire to stabilize the blood sugar level and avoid the oscillation between unhealthy high and low blood sugar levels in patients with liver disease as disclosed by Hansson et al.

No claim is allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to NANNETTE HOLLOMAN whose telephone number is (571) 270-5231. The examiner can normally be reached on Mon-Fri 800am-500pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. H./
Examiner, Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612